

### **REMARKS**

Claims 1-4, 8-11 and 61-62 are pending in this application upon entry of the claim amendments presented herein. Claims 5-7 are canceled without prejudice to Applicants' right to pursue the subject matter recited by them in one or more divisional, continuation, and/or continuation-in-part applications.

Claims 1-2 are amended to recite a specific topoisomerase inhibitor topotecan. Support for these amendments can be found, for example, on page 9, line 34 of the specification. In addition, claims 8-11 are amended to remove the recitation of the amounts of irinotecan or SN-38, since those topoisomerase inhibitors are not recited by claims 1-2 as amended. No new matter has been introduced.

Applicants respectfully submit that the pending rejections are allowable for at least the following reasons.

#### **I. The Rejection Under 35 U.S.C. § 103(a) Should be Withdrawn**

The Examiner maintains the rejection of claims 1-11 under 35 U.S.C. § 103(a) as allegedly unpatentable over Marx, Pitot, and Priel in combination. (Office Action, page 2). In addition, the Examiner rejects claims 61-62 as allegedly unpatentable over Marx, Pitot, and Priel in combination. (Office Action, page 6). Applicants respectfully traverse these rejections.

First, Applicants respectfully reiterate that the Examiner has not established a *prima facie* case of obviousness, as discussed in detail in their Response dated August 21, 2006. (See Applicants' Response of August 21, 2006, pages 3-5, incorporated herein by reference). As the Examiner does not offer any evidence or reasoning to the contrary in the Advisory Action, Applicants respectfully submit that the rejection should be withdrawn for this reason alone.

Furthermore, and perhaps more importantly, Applicants respectfully point out that sufficient superior results have been provided in the record to rebut any presumption of obviousness even assuming there were one.

In this regard, Applicants note that the Examiner's rejection is based on his allegation that the unexpected results provided in this application are not commensurate with the scope of the claims. (See Advisory Action, page 2). Although Applicants strongly disagree, particularly to the extent that the allegation that the results provided in the records are not

commensurate with the scope of the claims appears to be solely based on the results concerning the combination of irinotecan and thalidomide. (*See* Office Action, page 4). However, Applicants respectfully point out that results concerning the combination of topotecan and thalidomide was also provided in this application. (Applicants' Response of August 21, 2006, pages 8-9). Based on these results, Applicants pointed out that "one having ordinary skill in the art may be able to ascertain a trend in the exemplified data which would allow him to reasonably extend the probative value" of the results provided in the records. (*Id.*, citing *In re Kollman*, 595 F.2d 48, 56 (C.C.P.A. 1979)).

Be that as it may, however, claims 1 and 2 are amended herein to recite only "topotecan," a topoisomerase inhibitor for which the superior results have been previously provided in this application. Therefore, it is clear that the superior results provided would be commensurate with the scope of the claims. In other words, superior results for the specific combination were provided to show the patentability of the claims that recite the very combination, *i.e.*, topotecan and thalidomide. In view of this fact, Applicants respectfully submit that the pending claims are unobvious over the references cited by the Examiner, and thus, request that the rejection under 35 U.S.C. § 103 be withdrawn.

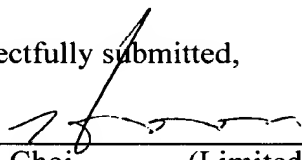
## **II. Conclusion**

For at least the foregoing reasons, Applicants respectfully submit that all of the pending claims are allowable, and thus, request that the rejections be withdrawn.

No fee is believed due for the submission of this paper. However, if any fees are due for the submission of this paper or to avoid abandonment of this application, please charge them to Deposit Account No. 50-3013.

Respectfully submitted,

Date: March 8, 2007

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